



Express Mail No.: EV 452 774 228 US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of:	Srivastava and Chandawarkar	Confirmation No.:	2913
Serial No.:	10/070,875	Art Unit:	1644
Filed:	August 21, 2002	Examiner:	SZPERKA, Michael Edward
For: METHODS AND COMPOSITIONS FOR THE TREATMENT AND PREVENTION OF GRAFT REJECTION USING HEAT SHOCK PROTEINS		Attorney Docket No:	8449-086-999 CAM # 708584-999085

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56 & § 1.97**

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This application is a §371 application of PCT/US00/24711, filed September 8, 2000, which is a continuation-in part of U.S. patent application no. 09/393,652, filed September 10, 1999.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent and Trademark Office of all references coming to the attention of Applicants or attorneys for Applicants which are or may be related to patentability of the claimed invention, Applicants hereby direct the Examiner's attention to references A01 to A07, B01-B08 and C01-C71, which are listed on the accompanying revised PTO Form 1449. Copies of references A01, A06, A07, C06, C22, C23, C35, C50, C54 and C67 are submitted herewith. Pursuant to 37 CFR 1.98(d), copies of the other listed references are not being submitted as such copies are available in the file of the application no. 09/393,652.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.



Pursuant to 37 C.F.R. §1.97, because this Information Disclosure Statement is being submitted before the first substantive Office Action, it is believed no fee is due. If, however, a fee is due, please charge any required fee to Jones Day Deposit Account No. 50-3013.

Date: January 13, 2005

Respectfully submitted,

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**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

ATTY DOCKET NO.

8449-086-999

APPLICATION NO

10/070,875

APPLICANT

Srivastava and Chandawarkar

FILING DATE

8/21/02

GROUP

1644

**U.S. PATENT DOCUMENTS**

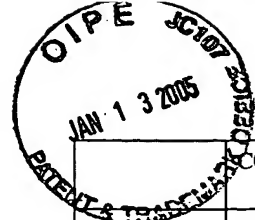
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	4,745,051	5/17/1988	Smith and Summers			
	A02	5,348,945	09/20/1994	Berberian et al.			
	A03	5,750,119	5/12/1998	Srivastava			
	A04	5,891,653	04/06/1999	Attfield			
	A05	5,993,803	11/30/1999	Cohen et al.			
	A06	6,312,711	11/6/01	Duchateau et al.			
	A07	6,709,672	3/23/04	Henot et al.			

**FOREIGN PATENT DOCUMENTS**

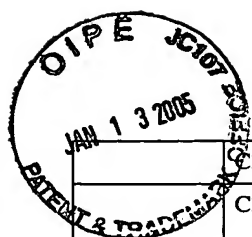
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	B01	WO 89/12455	12/28/1989	PCT				
	B02	WO 94/29459	12/22/1994	PCT				
	B03	WO 95/15338	06/08/1995	PCT				
	B04	WO 95/15339	06/08/1995	PCT				
	B05	WO 98/19167	05/07/1998	PCT				
	B06	WO 98/23735	06/04/1998	PCT				
	B07	WO 98/39029	09/11/1998	PCT			X	
	B08	WO02/072133	09/19/02	PCT				

**OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)**

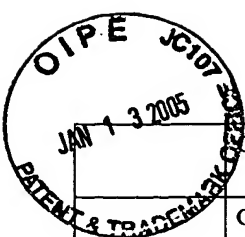
C01	Adamec et al., 1996, "Development of the surgical technique and tactics of combined pancreas and kidney transplantation with respect to the incidence of surgical complications", <i>Transplant. Proc.</i> <u>28</u> :3347
C02	Aichele et al., 1994, "Peptide-induced T-cell tolerance to prevent autoimmune diabetes in a transgenic mouse model", <i>Proc. Natl. Acad. Sci. USA</i> <u>91</u> : 444-448
C03	Bardwell and Craig, 1984, "Major heat shock gene of <i>Drosophila</i> and the <i>Escherichia coli</i> heat-inducible <i>dnaK</i> gene are homologous", <i>Proc. Natl. Acad. Sci. USA</i> <u>81</u> :848-852
C04	Barrios et al., 1992, "Mycobacterial heat-shock proteins as carrier molecules. ii: the use of the 70 kDa mycobacterial heat shock protein as carrier for conjugated vaccines can circumvent the need for adjuvants and <i>Bacillus Calmette guérin</i> priming", <i>Eur. J. Immunol.</i> <u>22</u> :1365-1372
C05	Birk et al., 1999, "The 60-kDa heat shock protein modulates allograft rejection," <i>Proc. Natl. Acad. Sci. USA</i> <u>96</u> : 5159-5163
C06	Bitter et al., 1987, "Expression and secretion vectors for yeast", <i>Methods Enzymol.</i> <u>153</u> :516-544
C07	Brunicardi, 1996, "Clinical islet transplantation: a consortium model", <i>Transplant. Proc.</i> <u>28</u> :2138-2140



C08	Chan, 1990, "Principles of Immunosuppression", <i>Critical Care Clinics</i> , W.B. Saunders Company, Philadelphia, 6:841-892
C09	Cohen, 1992, "Autoimmunity to hsp65 and the immunologic paradigm", <i>Adv. Internal Med.</i> <u>37</u> :295-311
C10	Cohen, 1991, "Autoimmunity to the chaperonins in the pathogenesis of arthritis and diabetes" <i>Ann. Rev. Immunol.</i> <u>9</u> :567-589
C11	Craig, 1993, "Chaperones: helpers along the pathways to protein folding", <i>Science</i> <u>260</u> :1902-1903
C12	Demotz et al., 1989, "Characterization of a naturally processed MHC class II-restricted T-Cell determinant of hen egg lysozyme", <i>Nature</i> <u>342</u> :682-684
C13	Elliott et al., 1990, "Naturally processed peptides", <i>Nature</i> <u>348</u> :195-197
C14	Falk et al., 1991, "Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules", <i>Nature</i> <u>351</u> :290-296
C15	Falk et al., 1990, "Cellular peptide composition governed by major histocompatibility complex class I molecules", <i>Nature</i> <u>348</u> :248-251
C16	First, 1998, "Clinical application of immunosuppressive agents in renal transplantation", <i>The Surgical Clinics of North America</i> , V. Rao, ed., W.B. Saunders Company, Philadelphia, <u>78</u> :61-76
C17	Gething and Sambrook, 1992, "Protein folding in the cell", <i>Nature</i> <u>355</u> :33-45
C18	Haeney, 1995, "The immunological background to transplantation", <i>J. Antimicrob. Chemother.</i> <u>36</u> (suppl.B):1-9
C19	Hamano et al., 1996, "Pancreas transplantation using non-suture cuff technique in the neck", <i>Kobe J. Med. Sci.</i> <u>42</u> :93-104
C20	Hickey et al., 1989, "Sequence and regulation of a gene encoding a human 89-kilodalton heat shock protein", <i>Mol. Cell. Biol.</i> <u>9</u> :2615-2626
C21	Hunt and Morimoto, 1985, "Conserved features of eukaryotic <i>hsp70</i> genes revealed by comparison with the nucleotide sequence of human <i>hsp70</i> ", <i>Proc. Natl. Acad. Sci. USA</i> <u>82</u> :6455-6459
C22	Inouye and Inouye, 1985, "Up-promoter mutations in the <i>lpp</i> gene of <i>Escherichia coli</i> ", <i>Nucleic Acids Res.</i> <u>13</u> :3101-3110
C23	Janknecht et al., 1991, "Rapid and efficient purification of native histidine-tagged protein expressed by recombinant vaccinia virus", <i>Proc Natl Acad Sci USA</i> <u>88</u> :8972-8976
C24	Jindal et al., 1989, "Primary structure of a human mitochondrial protein homologous to the bacterial and plant chaperonins and to the 65-kilodalton mycobacterial antigen", <i>Mol. Cell. Biol.</i> <u>9</u> :2279-2283
C25	Kasiske, 1998, "The evaluation of prospective renal transplant recipients and living donors", <i>The Surgical Clinics of North America</i> , V. Rao, ed., W.B. Saunders Company, Philadelphia, <u>78</u> :27-39
C26	Kendall and Robertson, 1996, "Pancreas and islet transplantation in humans", <i>Diabetes &amp; Metabolism (Paris)</i> <u>22</u> :157-163
C27	Kinkhabwala et al., 1996, "The role of whole organ pancreas transplantation in the treatment of type I diabetes", <i>Am. J. Surg.</i> <u>171</u> :516-520
C28	Lai et al., 1984, "Quantitation and intracellular localization of the 85K heat shock protein by using monoclonal and polyclonal antibodies", <i>Mol. Cell. Biol.</i> <u>4</u> :2802-2810
C29	Larsen and Stratta, 1996, "Pancreas transplantation: a treatment option for insulin-dependent diabetes mellitus", <i>Diabetes &amp; Metabolism (Paris)</i> <u>22</u> :139-146
C30	Lévy, et al., 1991, "ATP is required for in vitro assembly of MHC class I antigens but not for transfer of peptides across the ER membrane", <i>Cell</i> <u>67</u> :265-274
C31	Li and Srivastava, 1993, "Tumor rejection antigen gp96/grp94 is an ATPase: implications for protein folding and antigen presentation", <i>EMBO J.</i> <u>12</u> :3143-3151
C32	Lindquist and Craig, 1988, "The heat-shock proteins", <i>Annu. Rev. Genet.</i> <u>22</u> :631-677
C33	Liu et al., 1996, "Role of heat shock proteins in heart transplant rejection", <i>J. Heart and Lung Transpl.</i> <u>15</u> :222-228
C34	Lo et al., 1989, "Tolerance in transgenic mice expressing class II major histocompatibility complex on pancreatic acinar cells", <i>J. Exp. Med.</i> <u>170</u> :87-104
C35	Logan and Shenk, 1984, "Adenovirus tripartite leader sequence enhances translation of mRNAs late after infection" <i>Proc. Natl. Acad. Sci. USA</i> <u>81</u> :3655-3659
C36	Lussow et al., 1991, "Mycobacterial heat-shock proteins as carrier molecules", <i>Eur. J. Immunol.</i> <u>21</u> :2297-2302
C37	Maki et al., 1990, "Human homologue of murine tumor rejection antigen gp96: 5' - regulatory and coding regions and relationship to stress-induced proteins", <i>Proc. Natl. Acad. Sci. USA</i> <u>87</u> :5658-5662



C38	McFarland, 1996, "Complexities in the treatment of autoimmune disease", <i>Science</i> <b>274</b> :2037-2038
C39	Molitermo et al., 1995, Heat shock protein-induced T-lymphocyte propagation from endomyocardial biopsies in heart transplantation, <i>J. Heart Lung Transplant.</i> <b>14</b> :329-337
C40	Molitermo et al., 1995 "Heat shock protein reactivity of lymphocytes isolated from heterotopic rat cardiac allografts," <i>Transplantation</i> <b>59</b> : 598-604
C41	Mor et al., 1992, "T cells in the lesion of experimental autoimmune encephalomyelitis," <i>J. Clin. Invest.</i> <b>90</b> : 2447-2455
C42	Morton, 1998, "Early pregnancy factor: an extracellular chaperonin 10 homologue", <i>Immunol. Cell Biol.</i> <b>76</b> :483-496
C43	Mycko et al., 2004, "Inducible heat shock protein 70 promotes myelin autoantigen presentation by the HLA class II", <i>J Immunol.</i> <b>172</b> :202-213
C44	Nieland et al., 1996, "Isolation of an immunodominant viral peptide that is endogenously bound to the stress protein GP96/GRP94", <i>Proc. Natl. Acad. Sci. USA</i> <b>93</b> : 6135-6139
C45	Pakala et al., 1997, "T helper 2 (Th2) T cells induce acute pancreatitis and diabetes in immune-compromised nonobese diabetic (NOD) mice" <i>J. Exp. Med.</i> <b>186</b> :299-306
C46	Pockley, 2001, "Heat shock proteins, anti-heat shock protein reactivity and allograft rejection", <i>Transplantation</i> <b>71</b> :1503-1507
C47	Qian et al., 1995, "Expression of stress proteins and lymphocyte reactivity in heterotopic cardiac allografts undergoing cellular rejection", <i>Transplant Immunol.</i> <b>3</b> :114-123
C48	Rötzschke et al., 1990, "Characterization of naturally occurring minor histocompatibility peptides including H-4 and H-Y", <i>Science</i> <b>249</b> :283-287
C49	Rötzschke et al., 1990, "Isolation and analysis of naturally processed viral peptides as recognized by cytotoxic T cells", <i>Nature</i> <b>348</b> :252-254
C50	Ruther and Muller-Hill, 1983, "Easy identification of cDNA clones", <i>EMBO J.</i> <b>2</b> :1791-1794
C51	Sayegh and Krensky, 1996, "Novel immunotherapeutic strategies using MHC derived peptide", <i>Kidney Int.</i> <b>49</b> (Suppl. 53):S13-20
C52	Selmaj et al. 1991 "Colocalization of lymphocytes bearing $\gamma\delta$ T-cell receptor and heat shock protein hsp65 <sup>+</sup> oligodendrocytes in multiple sclerosis," <i>Proc. Natl. Acad. Sci. USA</i> <b>88</b> : 6452-6456
C53	Smilek et al., 1991, "A single amino acid change in a myelin basic protein peptide confers the capacity to prevent rather than induce experimental autoimmune encephalomyelitis", <i>Proc. Natl. Acad. Sci. USA</i> <b>88</b> : 9633-9637
C54	Smith, 1983, "Molecular engineering of the Autographa californica nuclear polyhedrosis virus genome: deletion mutations within the polyhedrin gene", <i>J. Virol.</i> <b>46</b> :584-593
C55	Solimena and DeCamilli, 1996, "From Th1 to Th2: diabetes immunotherapy shifts gears", <i>Nature Medicine</i> , <b>2</b> :1311-1312
C56	Srivastava et al., 1986, "Tumor rejection antigens of chemically induced sarcomas of inbred mice", <i>Proc. Natl. Acad. Sci. USA</i> <b>83</b> :3407-3411
C57	Suto and Srivastava, 1995, "A mechanism for the specific immunogenicity of heat shock protein-chaperoned peptides", <i>Science</i> <b>269</b> :1585-1588
C58	Tatusova et al., 1999, "Blast 2 sequences - a new tool for comparing protein and nucleotide sequences," <i>FEMS Microbiol. Lett.</i> <b>174</b> : 247-250
C59	Tisch and McDevitt, 1994, "Antigen-specific immunotherapy: is it a real possibility to combat T-cell-mediated autoimmunity?", <i>Proc Natl Acad Sci USA.</i> <b>91</b> :437-438
C60	Tydén et al., 1996, "Recurrence of autoimmune diabetes mellitus in recipients of cadaveric pancreatic grafts", <i>N. Eng. J. Med.</i> <b>335</b> :860-863
C61	Udono and Srivastava, 1993, "Heat shock protein 70-associated peptides elicit specific cancer immunity", <i>J. Exp. Med.</i> <b>178</b> :1391-1396
C62	Utsugi et al., 1994, "Prevention of recurrent diabetes in syngenic islet-transplanted NOD mice by transfusion of autoreactive T lymphocytes", <i>Transplantation</i> <b>57</b> :1799-1804
C63	Valente and Alexander, 1998, "Immunobiology of renal transplantation", <i>The Surgical Clinics of North America</i> , V. Rao, ed., W.B. Saunders Company, Philadelphia, <b>78</b> :1-26
C64	Van Bleek and Nathanson, 1990, "Isolation of an endogenously processed immunodominant viral peptide from the class I H-2K <sup>b</sup> molecule", <i>Nature</i> <b>348</b> :213-216
C65	Van Bogelen et al., 1987, "Induction of the heat shock regulon does not produce thermotolerance in <i>Escherichia coli</i> ", <i>Genes &amp; Development</i> <b>1</b> :525-531



C66	VanderVegt and Johnson, 1993, "Induction of long-term H-Y-specific tolerance in female mice given male lymphoid cells while transiently depleted of CD4+ or CD8+ T cells", J. Exp. Med. <u>177</u> :1587-1592
C67	Van Heeke and Schuster, 1989, "Expression of human asparagine synthetase in Escherichia coli", J. Biol. Chem. <u>264</u> :5503-5509
C68	Welch, 1993, "How cells respond to stress", Scientific American <u>268</u> :56-64
C69	Welch and Suhan, 1985, "Morphological study of the mammalian stress response: characterization of changes in cytoplasmic organelles, cytoskeleton, and nucleoli, and appearance of intranuclear actin filaments in rat fibroblasts after heat-shock treatment", J. Cell Biol. <u>101</u> :1198-1211
C70	Yamazaki et al., 1989, "Nucleotide sequence of a full-length cDNA for 90 kDa heat-shock protein from human peripheral blood lymphocytes", Nucl. Acids Res. <u>17</u> :7108
C71	Young, 1990, "Stress proteins and immunology", Annu. Rev. Immunol. <u>8</u> :401-420

**EXAMINER****DATE CONSIDERED**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.